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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDERSON, HEATHER L	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,621	LESAFFRE, LUCIEN	
	Examiner	Art Unit	
	Heather L. Anderson	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-35* is/are pending in the application.

4a) Of the above claim(s) *20-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *30-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/30/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election **without** traverse of Group III, claims 30-35 in the reply filed on 05 November 2007 is acknowledged.

Claims are 20-29 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 30-35 are presented for examination on the merits.

Information Disclosure Statement

The information disclosure statement filed 30 October 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Copies of two of the non-patent literature have not been provided.

The information disclosure statement has been placed in the application file, but the information referred to in the two non-patent literature publications in particular has not been considered.

Claim Objections

Claims 30, 32 and 34 are objected to because of the following informalities: each of these claims depend on withdrawn claim 20, which contains the phrase "cells walls of

yeast of the genus *Saccharomyces cerevisiae*. *Saccharomyces cerevisiae* is a species, not a genus. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 32-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter pertaining to the prevention of hyperglycemia which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is "undue," not "experimentation." " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual consideration." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of

experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

Claims 32 and 33 are drawn to a method of preventing hyperglycemia in a subject comprising administering a composition comprising yeast cell walls. While hyperglycemia is most often described as a symptom of diabetes, hyperglycemia merely means abnormally high blood sugar and is a relatively common occurrence in humans, particularly after meals (see, e.g., the dictionary.com reference and Temelkova-Kurktschiev et al., page 93, second column). Hyperglycemia can even be caused certain medications, so the prevention of hyperglycemia in all people and in all situations would be very problematic (see, e.g., Luna et al., page 1945, introduction). Additionally, please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treating." Therefore, establishing a method as being enabling for preventing hyperglycemia to a medical professional such as an endocrinologist would require a thorough and convincing amount of experimentation. The single working example in the specification of providing a supplement to a patient *already diagnosed* with diabetes provides evidence for a method of treatment of hyperglycemia, but is deficient for demonstration of "prevention" of hyperglycemia.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of ordinary skill in the art to employ the claimed method comprising administering the specified agent which would function in a manner so as to prevent hyperglycemia.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 30 -35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30, 32 and 34 are all dependent on withdrawn claim 20. Claim 20 is vague and indefinite due to the phrase "a total glucan and mannan content of at least 34% by mass." As this phrase has multiple possible interpretations, it is unclear what Applicant is claiming. It is not clear whether the individual amounts for glucan and for mannan are each required to be at least 34% by mass, or whether the amounts of both glycan and mannan when combined are an amount that is required to be at least 34% by mass. In the interest of compact prosecution, this phrase has been interpreted to mean the latter possibility given.

Claims 31, 33 and 35 are rendered vague and indefinite due to the phrase "in the case of." This expression makes the metes and bounds of these claims difficult to determine, because it is unclear what association hyperglycemia has with type 2 diabetes as claimed - is it merely co-present, or does one cause the other?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Jamas et al. (US 4,962,094).

Jamas et al. teach compositions of beta-glucans and methods of use (see, e.g., abstract and entire document). Yeast cells walls are used as a source of beta-glucans, but Jamas et al. note that the previous methods resulted in yeast cell wall glucans that were impure due to compounds such as glycogen (see column 1, lines 48-57). The beta-glucan product provided by Jamas et al. is 99-96% pure (see column 3, lines 58-59). The glycogen content of this product is determined and given in Table 3 as 2.9% (see column 8). The claims as currently written do not require the presence of both glucan and mannan, but allow for the agent of claim 20 to be either all glucan or mannan. Indeed, as noted in the instant specification, the process used by Applicant to produce the agent of claim 20 results in yeast cell walls that may not contain any mannans at all (see page 4, lines 38-39).

The composition of Jamas et al. is used for many possible reasons, such as bulking agent or for improving digestion, and administered in many forms, and thus this composition would be administered to any human subject (see column 2, lines 35-44). Stabilizing glycemia and/or treating hyperglycemia is also a concern for every human

subject due to various food choices or other factors like medication, so the population of subjects for each of the claimed methods would be the same population as the population to which the composition of Jamas et al. would be administered. Therefore, the instantly claimed methods involving the administration of the agent according to claim 20 would be inherently practiced by the administration of the composition of Jamas et al. to the same population.

In conclusion, the methods of claims 30 and 34-35 are drawn to the same method steps (administering the claimed composition), the same composition (as explained above), and the same population (all humans) as the method of administering the composition of Jamas et al. Although the claimed methods recite different intended results after administration, practicing one method would inherently be practicing the other method because the compound that is being administered has the same properties and thus would produce the same results.

Therefore the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 30-31 and 34-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Jamas et al. (US 4,962,094) in view of Wursch et al. (Diabetes Care, 1997).

Jamas et al. teach compositions of beta-glucans and methods of use (see, e.g., abstract and entire document). Yeast cells walls are used as a source of beta-glucans, but Jamas et al. note that the previous methods resulted in yeast cell wall glucans that were impure due to compounds such as glycogen (see column 1, lines 48-57). The beta-glucan product provided by Jamas et al. is 99-96% pure (see column 3, lines 58-59). The glycogen content of this product is determined and given in Table 3 as 2.9% (see column 8). The claims as currently written do not require the presence of both glucan and mannan, but allow for the agent of claim 20 to be either all glucan or mannan. Indeed, as noted in the instant specification, the process used by Applicant to produce the agent of claim 20 results in yeast cell walls that may not contain any mannans at all (see page 4, lines 38-39).

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In conclusion, the methods of claims 30 and 34-35 are drawn to the same method steps (administering the claimed composition), the same composition (as explained above), and the same population (all humans) as the method of administering the composition of Jamas et al. Although the claimed methods recite different intended results after administration, practicing one method would inherently be practicing the other method because the compound that is being administered has the same properties and thus would produce the same results.

Jamas et al. does not teach the specific administration of the composition to subjects with type II diabetes.

Wursch et al. teach that "diabetic individuals should benefit from diets that are high in soluble fiber beta-glucan" (see, e.g., page 1779, second paragraph and entire document).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the beta-glucan composition of Jamas et al. to not just treat hyperglycemia but also to treat subjects with type II diabetes, which

would intrinsically hyperglycemia in these subjects, as suggested by Wursch et al., which teaches that beta-glucan compositions should be consumed by diabetic patients, and produce the instant invention. One of ordinary skill in the art would have been motivated to do this because the inclusion of beta-glucan in the diet of a diabetic subject has been shown to be beneficial as taught by Wursch et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather L. Anderson whose telephone number is (571) 270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HLA

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